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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,796	10/10/2006	Patrick Faulkner	PB60770USW	4682

23347 7590 02/11/2008

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
02/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,796	FAULKNER ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 25, 31* is/are pending in the application.

4a) Of the above claim(s) *1 - 13, 15, 21 - 25, 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 16 - 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

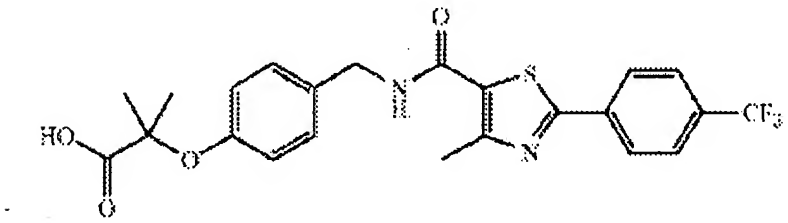
Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group II and a active substance of compound (1),



, in the reply filed on December 13, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1 – 25 and 31 are pending. Claims 1 – 13, 15, 21 – 25 and 31 are withdrawn as not being drawn to the elected invention. Claims 14 and 16 – 20 are currently under examination.

Specification

2. The disclosure is objected to because of the following informalities: essential subject matter to the claims is not included in the specification. The definition of form 2 and form 6 of compound (1) is simply cited as being present in WO 02/096893. Even if this material was incorporated by reference, the disclosure would still be objected to as incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 16 – 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to encompass

solvates, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these solvates meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. The specification does not disclose the solvent and stoichiometry of any solvates of compound (1).

5. Claims 17 – 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to encompass physiologically functional derivatives of compound (1), which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these physiologically functional derivatives meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. The specification does not disclose any requirements as to a physiologically functional derivatives of compound (1).

6. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The description and physical characetristics of form 2 and form 6 of compound (1) is critical or essential to the practice of the invention, but is not included in the claim(s) or the disclosure. Without this information, what form 2 and form 6 are and how these claimed forms of compound (1) differ from compound (1) itself and the other form cannot be determined.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 14, 16 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer et al. (WO 02/096893).

Boyer et al. discloses 2-methyl-2-[4-{[(4-methyl-2-[4-trifluoromethylphenyl]-thiazol-5ylcarbonyl)amino]rnethyl}phenoxy] propionic acid (compound (1) of the instant application) as an peroxisome proliferator activates receptor (PPAR) alpha activator, polymorphs of this compound and pharmaceutical compositions containing them (p 1, ln 5 – 10). The compounds can be utilized as pharmaceutically acceptable salts or solvates (p 12, ln 12 – 14). The administration of hydrolysable esters of compounds of the same general formula as compound (1) is also disclosed (p 2, ln 22 – 29). Two particular polymorphs, "form 2" and "form 6" are defined by specific physical properties (melting point and X-ray diffraction data; p 5, ln 4 – 6).

The compounds disclosed in Boyer et al. (including the polymorphic forms 2 and 6), can be administered in the form of pharmaceutical compositions in an admixture of the active agent with one or more physiologically acceptable carriers or excipients (p 12, ln 32 – p 13, ln 2). While the amount of the compound administered can vary based on a number of factors, doses employed for adult human treatment will typicall be in the range of 0.02 – 5,000 mg/day (20 – 5,000,000 µg/day; p 16, ln 3 – 8). While the daily dose can be presented in a single dose, a divided dose of one, two, three, four or more sub-doses per day is also disclosed (p 16, ln 8 – 11).

The presented range of dosages overlaps with the range of amounts of compound (1) present in claims 16. If instead of a once daily pharmaceutical preparation, a twice or three times a day pharmaceutical preparation is prepared, a 20 µg daily dose becomes a pharmaceutical composition comprising 10 and 8.3 µg of compound (1) respectively. These values are encompassed by the ranges of active agent present in claims 17 – 20.

Claim 14 is a product-by-process claim. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. The process of manufacture recited in claim 1 is known to those of ordinary skill in the art and there is no indication that the

process described in claim 1 results in a pharmaceutical composition that is patentably distinct from the compositions disclosed in the prior art.

Given the teachings of Boyer et al., one of ordinary skill in the art would have a reasonable expectation of success to formulate the pharmaceutical composition of the instant claims with the amount of active ingredient present. This renders the claims of the instant application obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Claims 14 and 16 – 20 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 7:30 a.m. - 5 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER